Department of Veteran Affairs
Veterans Health Administration
Washington, DC 20420

M-3, Part I
Chapter 15

July 12, 1993

1. Transmitted is a new chapter to the Department of Veterans Affairs, Veterans Health Administration Manual M-3, "Research and Development in Medicine," Part I, "General," Chapter 15, "Policies and Procedures for Dealing with Possible Misconduct in Scientific Research."

2. The principal purpose of chapter 15 is to set policy for dealing with misconduct of investigators involved in scientific research.

3. Filing Instructions

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4. RESCISSION: VHA Directive 10-92-014 is rescinded.

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Distribution: RPC: 1371 is assigned
FD

Printing Date: 7/93

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RESCISSIONS

The following material is rescinded:

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CHAPTER 15. MISCONDUCT IN SCIENTIFIC RESEARCH

15.01 PURPOSE

The purpose of this chapter is to define "misconduct in scientific research," and to establish policies and procedures for the reporting, investigating, and resolving of complaints alleging scientific misconduct by VA (Department of Veterans Affairs) investigators. The procedures are designed to protect public confidence in the integrity of research conducted in VA, and at the same time, protect the rights and reputations of individuals accused of misconduct.

15.02 POLICY

It is the policy of VA's R&D (Research and Development) Program to require high ethical standards for all research activities and, if necessary, to inquire, investigate, and resolve promptly and fairly all alleged, or apparent misconduct in science. The R&D Program management will take appropriate action against individuals if it is determined that misconduct has occurred.

15.03 SCOPE

a. The policies and procedures described in this chapter apply to all instances of alleged, or apparent, misconduct involving research, research training, and related activities conducted by VA investigators regardless of source of funding (or even if unfunded). NOTE: Issues that are not primarily scientific are outside the scope of this chapter, for example, conflicts of interest, sexual harassment, etc.

b. Investigators receiving support from other Federal agencies such as the National Institutes of Health, or the National Science Foundation, may be subject to additional scientific misconduct policies such as those contained in 42 CFR (Code of Federal Regulations) Subpart A (Public Health Service), or 45 CFR 689.1 through 689.9 (National Science Foundation).

15.04 DEFINITION

"Misconduct" is defined as:

a. Serious deviation, such as fabrication, falsification, or plagiarism, from accepted practice, in carrying out research, or in reporting the results of research; or

b. Material failure to comply with Federal requirements affecting specific aspects of the conduct of research e.g., the protection of human subjects and the welfare of laboratory animals.

15.05 GENERAL RESPONSIBILITIES

a. The scientific community in general, and VA investigators in particular, are expected to make every effort to prevent scientific misconduct.

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b. Primary responsibility for ensuring the authenticity of reported data rests with the principal investigator. In addition, all investigators identified as authors of a report also assume responsibility for its authenticity. An investigator must not knowingly represent as empirical observations data which are newly synthesized, or arbitrarily altered.

c. The appropriate response to a complaint of fraudulent presentation of data is to review the original experimental records. All investigators have the responsibility to maintain a record of all experimental protocols and data sufficient to allow subsequent verification. Written, detailed, and explicit procedures for data gathering, storage, retrieval and analysis must be available in all laboratories. Data must be retained for a minimum of 5 years.

d. Principal investigators have the responsibility to ensure proper supervision of the research not performed directly by them. Trainees must be supervised by experienced scientists, and they should be encouraged to present their studies at review sessions or seminars. Publications must give credit to all investigators involved in the research, and all publications must be approved by all co-authors.

e. VHA (Veterans Health Administration) field facilities must ensure that sufficient management controls are in effect to preclude the occurrences of all unethical scientific practices in research. Examples of violations of ethical standards include:

(1) Deliberate fabrication, or falsification, in the conduct, or reporting, of research data;

(2) Plagiarism in scientific publications, or in applications for research support;

(3) Practices which seriously deviate from those commonly accepted within the scientific community for proposing, reporting or conducting research;

(4) Misappropriation of research funds;

(5) Violation of laws established for the protection of human and animal subjects; and

(6) Retaliation against any individual making allegations of misconduct.

15.06 PROCEDURES FOR RESPONDING TO ALLEGATIONS OF SCIENTIFIC MISCONDUCT

The following procedures form the framework when dealing with instances of alleged unethical scientific practice in VA research:

a. Allegations of unethical practices, which must be in writing, are first reported to the immediate supervisor of the investigator(s) whose actions are in question.

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b. The supervisor is expected to report these allegations promptly to the ACOS (Associate Chief of Staff) for Research and Development, whereupon the ACOS will notify the COS (Chief of Staff).

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NOTE: In some instances, the allegations may be resolved through an information fact-finding inquiry among the parties involved. If the allegations are clearly frivolous, self-serving, vindictive, or without supporting documentation, no further action is required; however it would be prudent to retain a record of such inquiries in the event that subsequent allegations are raised which involve issues that were previously reviewed.

c. A fact-finding inquiry must be thorough (including examinations of data, animals, humans, or budgets in question) and sufficient to withstand higher review if the matter is not withdrawn or terminated.

d. If the preliminary inquiry determines that evidence of unethical scientific practices exists, the COS will refer the matter promptly to the VA medical center Director.

e. When the investigator, who is the subject of the allegation, is also a faculty member of an affiliated medical school, the medical center Director, or COS, will notify the Dean of the affiliated medical school.

f. If the available evidence suggests a violation of criminal law, the matter must be referred to the Office of the Inspector General.

g. If the medical center Director, COS, and Dean of the affiliated medical school, determine that substantial evidence suggesting unethical scientific practice is available, they will form a committee to investigate the allegations.

h. A mutually acceptable determination must be made regarding whether the medical school or VA will have the primary responsibility for coordinating the investigation.

i. The committee must consist of members from the staff of the VA medical center and the faculty of the affiliated university who possess research expertise. One individual should be appointed to the committee who will be charged with gathering and evaluating evidence. Unless the circumstances indicate otherwise, the ACOS for R&D, or designee, should chair the committee and issue the final report of the findings.

j. Individuals from outside the VA medical center, with expertise in the same area of science as the researcher(s) whose practice is in question, may also be added to the committee.

k. If the alleged unethical practice involves the abuse of humans, or animals, the committee is expected to have an active liaison with a representative of the Institutional Review Board, or the Animal Studies Subcommittee.

l. At the initiation of the investigation, the accused researcher(s) must be notified immediately, in writing, of the allegations and that a committee of investigation has been formed to consider the allegations. The accused researcher(s) must be informed of the right to be represented by legal counsel or other personal representative(s). NOTE: The personal representative(s) may act only in an advisory capacity.

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m. The medical center Director and the Dean of the affiliated medical school, will determine when other interested parties, such as collaborators, supervisors and agencies sponsoring, or funding, the researcher(s) in question, are to be informed of the pending investigation. In making this determination, consideration should be made to whether preliminary evidence indicates that a serious question concerning the validity of the research exists.

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n. Once the investigation stage begins, the ACOS for R&D, or designee, must notify the appropriate VA Central Office service (e.g., Medical Research, Health Services R&D, or Rehabilitation R&D) of the investigation, with a critical summary of the facts of the incident. The ACOS, or designee, must keep the medical center Director informed regarding the progress of the investigation.

o. The committee has discretion in choosing the manner of inquiry which may include one or more of the following:

(1) The securing and review of documentary evidence including all original experimental records, protocol, and data;

(2) Interviewing relevant persons, whether in person, or by telephone;

(3) Group meetings of discussion or inquiry; and/or

(4) Hearings. If hearings are conducted, sessions of the hearings must be closed so that a fair and judicious investigation, which protects the rights and reputation of all involved, can be maintained. Records of the inquiry will be disclosed only in accordance with law.

p. Files maintained by VA in conjunction with the investigation will not be retrievable by personal identifiers (e.g., name, Social Security Number, etc.). If an Agency employee fails to observe this prohibition and maintains investigation records retrieved by personal identifiers, such conduct may constitute a violation of the Privacy Act, i.e., 5 U.S.C. (United States Code) 552a. This violation may lead to a Federal Court imposing civil sanctions against VA and criminal penalties against the responsible employee, and/or appropriate disciplinary action.

q. The subject(s) of the allegation and individual making the accusations must be interviewed by the committee of investigation. Both parties will have the opportunity to offer comments and other relevant information and to propose witnesses. The committee will ensure that the information collected is recorded properly and that confidentiality is maintained.

r. The length of time from reporting an instance of possible misconduct to completion of the investigation should not exceed 3 to 6 months, unless circumstances are exceptional. If interval progress reports are made by the investigation committee, they must be provided to the medical center Director, COS, the Dean of the affiliated medical school, and the Director of the appropriate VA Central Office Service.

s. A written summary, which must include the content of the summary described in subparagraph 15.06n., of the investigation must be made available to the researcher(s) for comment and rebuttal. If the text of the summary is acceptable in principle, the signatures of the researchers should so stipulate.

15.07 PROCEDURES TO BE TAKEN FOLLOWING COMPLETION OF THE INVESTIGATION AND RECEIPT OF COMMENTS OF INVOLVED RESEARCHER(S)

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a. If the alleged unethical scientific practices are not confirmed by the investigation, the medical center Director, COS, and Dean of the affiliated medical school, must take appropriate action to ensure that the reputation of the individual(s) under investigation is cleared of suspicion.

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b. Other interested parties, such as collaborators, supervisors and agencies sponsoring, or funding, the research, must be notified that the individual(s) suspected to have engaged in alleged unethical practice was absolved of wrong doing by the investigator.

c. The individual(s) must be given the option of having a written notice of clearance sent to the relevant members of the faculty from the Dean of the affiliated medical school, and the VA medical center Director.

d. If there is evidence of unethical scientific practice, a written report (RCS (Reports Control System) 10-0758) of the finding must be sent by the ACOS for R&D or Coordinator for R&D, to the medical center Director, the Dean and President of the affiliated medical school, the VA Central Office Director of Medical Research Service (or other appropriate R&D service), and other agencies sponsoring or funding the researcher(s).

e. After reviewing the report (RCS 10-0758), the Dean of the affiliated medical school and the medical center Director must prepare a written summary of the findings to include recommendations for administrative action to prevent future instances of unethical practices. This summary plus a description of corrective action taken against the researcher(s), if any, must be submitted promptly the Director, Medical Research Service, VA Central Office (or other aprropriate R&D service), who with appropriate consultation, will make a descision regarding the research funding of the investigator(s). The Director, Medical Research Service, VA Central Office (or other appropriate R&D service), will communicate the outcome of the entire process to the Under Secretary for Health.

f. The medical center Director, COS, and Dean of the affiliated medical school, will take action to have all pending abstracts and papers associated with the unethical scientific practices of the researcher(s), withdrawn; they must notify editors of journals in which previous abstracts, articles, and papers relating to the research in question, were published.

g. The medical center Director, Dean of the affiliated medical school, and Under Secretary for Health, in consultation with legal counsel, should decide if the release of information, regarding the scientific misconduct, to the media is warrented.